REMARKS

I. Status of the Claims and Amendments

Applicant acknowledges the Office's corrective action regarding the inadvertent omission of pyridyl compounds of claim 13. As indicated in the Office Action, "the scope of group I would be Ar^2 as delineated in claim 6, i.e. phenyl or monocyclic aromatic heterocycles." Office Action, page 2. The Office states that "[c]laims 10-13 and claims 5-9, 14-17 reading on R^4 is Formula II X is $C(-R^{27}-)-R^{28}$ or NR^{26}, m=n =2, Ar^2 is phenyl or monocylic aromatic heterocycles are prosecuted." *Id.* Claims 1-4, in full, and claims 5-9 and 14-17, to the extent they encompass non-elected subject matter, stand withdrawn from consideration. *Id.*

Applicants have cancelled non-elected claims 1-4 without prejudice or disclaimer of their right to pursue the subject matter of those claims in one or more divisional applications. Claim 6 has been cancelled and it subject matter incorporated into claim 5. Claim 15-17 have also been cancelled without prejudice or disclaimer.

Claim 5 has been rewritten in independent form and to incorporate the elected invention as recited in claim 6. Support for those amendments can be found in cancelled claims 1 and 6. In view of the cancellation of claim 6, Applicants have amended claim 7 to depend from claim 5. An extra period has been removed from claims 9 and 12. Applicants have rewritten claim 13 in independent form. Finally, Applicants have amended claim 14 to make explicit that the composition comprises a pharmaceutically acceptable carrier. Support for this amendment is found in the description of the various pharmaceutically acceptable carriers found in the specification on pages 36-38. These amendments do not add any new matter.

II. Priority Claim

The Office denied Applicant's claim to the benefit of foreign priority based upon Japanese Patent Application Nos. JP 02-10413 and JP 02-10447 because "no certified translation of the priority documents were submitted." Office Action, page 2.

In response to the Office Action, Applicants submit English translations of both Japanese Patent Applications. Accordingly, they respectfully request that the Office acknowledge that the current claims are entitled to benefit of priority of those applications. Applicants note for completeness that a valid claim to priority was submitted in this application and the certified copies of the Japanese applications of which the benefit of foreign priority was claimed were filed on July 8, 2004. There is no requirement under 35 U.S.C. § 119 to provide a verified translation of priority documents that are not in the English language in order to perfect the priority claim. Instead, a translation is only required if the application is involved in an interference, if it is necessary to overcome the date of a cited reference, or the Examiner specifically requires it. 37 C.F.R. § 1.55(a)(4).

III. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office rejects claims 14-17 under 35 U.S.C. § 112, ¶2, as allegedly indefinite. Office Action, page 2. The Office notes that it finds various terms unclear and requests clarification. *Id.*

Without necessarily agreeing with the Office's position, Applicants have cancelled claims 15-17. They note that this cancellation does not in any way affect the scope of the pending composition claims, since claims 15-17 merely recited intended uses or inherent properties of compounds within the scope of the currently pending

claims. In addition, they have amended claim 14 to clarify that it is a composition formulated with a pharmaceutically acceptable carrier.

Applicants respectfully request that the Office withdraw the rejections.

IV. Rejection Under 35 U.S.C. § 102

A. 35 U.S.C. § 102(a) Rejection

Claims 5-11 and 14-17 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by CA: 137 63257 to Muto et al. ("Muto"). Office Action, page 3. The Office draws Applicants' attention to RN 439146-08-4 and RN 439146-12-0. *Id.*

Applicants enclose verified English translations of the foreign priority documents of which benefit is claimed. They respectfully submit that the claimed subject matter is supported in those documents and so is entitled to a priority date of January 18, 2002. Muto appears to correspond to WO 03/103657, which published on December 18, 2003, a date that is after Applicants' the January 18, 2002, foreign priority date. Accordingly, Muto is not prior art to the pending claims and cannot be relied upon as a 102(a) anticipatory reference. Applicants respectfully request that the Office withdraw this rejection.

B. 35 U.S.C. § 102(e) Rejection

The Office rejects claims 5-17 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent Application Publication No. 2004/0077697. Office Action, page 3. It is the Office's position that the "piperidin/piperazinyl species of the whole reference anticipated the instant claims." *Id.* Applicants respectfully traverse this rejection.

To anticipate a claim under 35 U.S.C. § 102, every element recited in the claim must be disclosed in the reference. *See Verdegaal Bros. v. Union Oil Co. of California*,

2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.") Further, a reference must "clearly and unequivocally disclose the claimed [composition] or direct those skilled in the art to the [composition] without any need for picking, choosing, and combining various disclosures . . . ." *In re Arkley*, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972).

Claim 5 as originally presented included definitions for various substituents that were based on definitions presented in claim 1. Specifically, Ar^2 in the general formula (V) of Claim 5 was defined as Ar^1 of Claim 1. In claim 1, Ar^1 included a proviso such that that when R^1 (R^3 in claim 5) is aryl or pyridyl, each of which may be substituted with one or more groups selected from the group consisting of lower alkyl, -CO-lower alkyl, -COO-lower alkyl, -OH, -O-lower alkyl, -OCO-lower alkyl, and halogen, and R^2 (R^4 in claim 5) is a group represented by the following general Formula (II); Ar^1 (i.e., Ar^2) is not phenyl or pyridyl, each of which may be substituted with one or more groups selected from the group consisting of lower alkyl, -CO-lower alkyl, -COO-lower alkyl, -OH, -O-lower alkyl, -OCO-lower alkyl, and halogen.

US 2004/0077697 discloses compounds of the general formula (I). E.g., paragraph [0016]. In formula (I), Ar is either phenyl or pyridyl, each of which may be substituted with one or more groups selected from the group consisting of lower alkyl, -CO-lower alkyl, -COO-lower alkyl, -OH, -O-lower alkyl, -OCO-lower alkyl, and halogen. Paragraph [0018]. This position corresponds to Ar^2 in the current compound. Formula (I) of US 2004/0077697 defines its R^1 position as an aryl or pyridyl, each of which may be substituted with one or more groups selected from the group consisting of lower

alkyl, -CO-lower alkyl, -COO-lower alkyl, -OH, -O-lower alkyl, -OCO-lower alkyl, and halogen. Paragraph [0019]. This position corresponds to R^3 in the claimed compounds. Finally, US 2004/0077697 only contemplates a cyclic amino at the 5-position of thiazole ring. Paragraphs [0016], [0020], and [0021].

Applicants respectfully submit that in view of the definitions and proviso language in the current application and the definitions in US 2004/0077697, the claimed compounds are distinct from the compounds disclosed in US 2004/0077697. Accordingly, claims 5-17 are not anticipated by that reference and Applicants respectfully request the Office to withdraw the rejection.

Applicants also respectfully submit that the rejection is in error because US 2004/0077697 is not available as a reference under 35 U.S. C. § 102(e). US 2004/0077697 published on April 22, 2004. It is based upon application no. 10/470,917, which is the National Stage of International Application No. PCT/JP02/00755. That application published as WO02/062775 on Aug. 15, 2002. It did not, however, publish in the English language. Accordingly, US 2004/0077697 does not meet all of the requirements of 35 U.S.C. § 102(e), as discussed in M.P.E.P. § 706.02(f)(1)(I)(C). The Office therefore may not rely upon that reference for any date other than its publication date, which is after this application's January 15, 2003, international filing date..

Applicants note that WO02/062775 published on Aug. 15, 2002, which is less than one year before the January 15, 2003, international filing date of the current application. Accordingly, WO02/062775 is theoretically available as a reference against this application under 35 U.S.C. § 102(a). However, in view of the verified translations provided with this response, Applicants respectfully submit that the claims are entitled to

benefit of the January 18, 2002, filing date of the Japanese priority applications. Accordingly, Applicants have antedated the publication date of WO02/062775, irrespective of any determination the Office might make regarding the subject matter therein.

US 2004/0077697 is not available as a reference under 35 U.S.C. § 102(e) and does not disclose the same invention. Applicants therefore respectfully ask that the Office withdraw the rejection based upon it.

C. 35 U.S.C. § 102(f) or (g) Requirement

In addition to rejecting claims 5-17 under 35 U.S.C. § 102(e), the Office took the position that "claims 5-17 are directed to the same invention as that disclosed in commonly assigned U.S. Patent Application Publication No. 2004/0077697" and that "the issue of priority under 35 U.S.C. 102(f) and (g) of this identical invention (anticipatory compounds) must be resolved." Office Action, page 3. The Office required the assignee to state which entity is the prior inventor of the conflicting subject matter. *Id.*

As discussed supra in part IV.B, the current claims and the compounds disclosed in US 2004/0077697 are distinct. Further, every inventor of the current application should be an inventor of each claim, if the 4-position of the thiazole ring is not limited to a heteroaryl other than pyridyl. Because the claimed subject matter in US 2004/0077697 and the claimed subject matter in the current application are distinct, Applicants respectfully submit that the requirement was in error. Accordingly, they ask that the Office withdraw this requirement.

V. Rejection Under 35 U.S.C. § 112, First Paragraph

The Office rejects claims 5-12 and 14-17 under 35 U.S.C. § 112, ¶1, as allegedly lacking enabling support in the specification Office Action, page 4. In support of its position, the Office points to various references that share part of the core structure but differ in a particular substituent, and notes that those compound have alternate activities. *Id.* Applicants respectfully traverse this rejection.

As an initial matter, Applicants note that claims 15-17 have been cancelled without disclaimer or prejudice. Claim 5 has been rewritten in independent form.

The Office alleges that various references document that manipulation of the various substituents of the core compound will cause different activities. It is the Office's position that because certain non-analogous references (e.g., 5,380,736) demonstrate that changes in structure cause changes in therapeutic activity, that (i) such changes are applicable to the presently claimed compounds, and (ii) that if that is true, then the claims are not enabled.

It is respectfully submitted that both premises are incorrect. First, Applicants have exemplified and tested multiple compounds falling within the claimed genus of compounds and demonstrated that those compounds possess the same type of therapeutic activity using three different assays. For example, Applicants have already shown that ten of the compounds of the invention are able to stimulate proliferation of human c-mpl-Ba/F3 cells comparably to the stimulatory effect of recombination human thrombopoietin (TPO). Table 1, found on page 34 of the specification, shows an efficacy range for the ten test compounds of from 87% to 107%. The tested compound of Example 16 in Table 1 corresponds to the elected species (1-(3-chloro-5-{[4-

(4chlorothiophen-2-yl)-5-(4-cyclohexylpiperazin-1-yl)thiazol-2-yl]carbamoyl}-2-pyridyl)piperidine-4-carboxylic acid). That compounds had an efficacy of 93%. Applicants have also shown that compounds of the invention promote the formation of megakaryocytic colonies. Specification, page 35. In addition, Applicants have verified that eight test compounds are orally available by administering those compounds to mice then showing that plasma obtained from the dosed mice can cause human c-mpl-Ba/F3 cell to proliferate. Specification, pages 35 and 36. In this assay, too, the elected compound elected species (1-(3-chloro-5-{[4-(4chlorothiophen-2-yl)-5-(4-cyclohexylpiperazin-1-yl)thiazol-2-yl]carbamoyl}-2-pyridyl)piperidine-4-carboxylic acid) (corresponding to "Example 16") had an efficacy of greater than 80%. Thus, Applicants have already provided the Office with data demonstrating that multiple compounds within the scope of the claims possess the same activities.

Applicants remind the Office that "it is not necessary that all of the compounds claimed be useful for every utility disclosed in an application." *Ex parte Cole,* 223 USPQ 94, 95 (PTO Bd. 1983). Thus, even considering the various Chemical Abstracts citations, the fact that some compounds within the scope of the claims may have different and/or additional utilities does not in any way bar their patentability in the present application.

Because the specification provides adequate guidance such that the skilled artisan could both make and use the claimed compounds without undue experimentation, Applicants respectfully submit that the rejection was in error. Accordingly, they request that the Office withdraw it.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account no. 06-0916.

Respectfully submitted,

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